

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lee R. Brettman, Judith A. Fox and David Edward Allison

Continuation Application of

Application No.: 09/748,960

Filed: December 27, 2000

For: METHOD OF ADMINISTERING AN ANTIBODY

Date: <u>December 15, 2003</u>	
EXPRESS MAIL LABEL NO.	<u>EV 215731109 US</u>

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references AL-AQ, AL2-AQ2, AL3, AR-AZ, AR2-AZ2, AR3-AZ3, AR4-AZ4 and AR5-AU5 are enclosed.
 - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 08/700,737, by Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones, Walter Newman, José Saldanha and Mary M. Bendig, filed August 15, 1996, Docket No.: 1855.1017-000

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[X] A copy of the above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Robert H. Underwood
Robert H. Underwood
Registration No.: 45,170
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: *December 15, 2003*

PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 1855.2007-010		APPLICATION NO.	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION December 12, 2003 (Use several sheets if necessary)				APPLICANT Lee R. Brettman et al.			
				FILING DATE		GROUP	

U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,932,214	03-AUG-99	Lobb et al.	424	144.1	
	AE	5,871,734	16-FEB-99	Lobb et al.	424	144.1	
	AC	5,888,507	30-MAR-99	Burkly	424	130.1	
	AD	5,840,299	24-NOV-98	Bendig et al.	424	133.1	
	AE	5,538,724	23-JUL-96	Butcher et al.	424	152.1	
	AF	5,403,919	04-APR-95	Butcher	530	388.22	
	AG	4,816,397	28-MAR-89	Boss et al.	435	68	
	AH	5,225,539	06-JUL-93	Winter	530	387.3	
	AI	5,624,821	29-APR-97	Winter et al.	435	69.6	
	AJ	5,585,089	17-DEC-96	Queen et al.	424	133.1	
	AK	5,821,337	13-OCT-98	Carter et al.	530	387.3	
	AA2	5,859,205	12-JAN-99	Adair et al.	530	387.3	
	AB2	4,816,567	28-MAR-89	Cabilly et al.	530	387	

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 93/15764	19-AUG-93	PCT			
	AM	WO 94/17828	18-AUG-94	PCT			
	AN	WO 97/18838	29-MAY-97	PCT			
	AO	WO 90/07321	12-JUL-90	PCT			
	AP	WO 94/16094	21-JUL-94	PCT			
	AD	WO 95/19790	27-JUL-95	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	AR Pulido, R. et al., "Functional Evidence for Three Distinct and Independently Inhibitable Adhesion Activities Mediated by the Human Integrin VLA-4," <i>The Journal of Biological Chemistry</i> , 266(16):10241-10245 (1991).
	AS Katz, J.A., "Medical and Surgical Management of Severe Colitis," <i>Seminars in Gastrointestinal Disease</i> , 11(1):18-32 (2000).
	AT Sachar, D.B., "How to do Without Steroids in Inflammatory Bowel Disease," <i>Inflammatory Bowel Diseases</i> , 6(1):58 (2000).

EXAMINER	DATE CONSIDERED
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U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AC2	5,834,021	10-NOV-1998	Spiers	424	490	
	AD2	6,015,662	18-JAN-2000	Hackett, Jr. et al.	435	5	
	AE2	6,551,593	22-APR-2003	Ringler et al.	424	143.1	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL2	JP 6303990	01-NOV-94	Japan			X
	AM2	EP 0303463 B1	15-FEB-89	EPO			
	AN2	WO 94/13312	23-JUN-94	PCT			
	AO2	WO 94/29351	22-DEC-94	PCT			
	AP2	WO 91/09967	11-JUL-91	PCT			
	AQ2	WO 88/07089	22-SEP-88	PCT			
	AL3	WO 98/06248	19-FEB-1998	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU	Present, D.H., "How to do Without Steroids in Inflammatory Bowel Disease," <i>Inflammatory Bowel Diseases</i> , 6(1):48-57 (2000).					
	AV	Vasiliauskas, E.A., "An Open-Label Pilot Study of Low-Dose Thalidomide in Chronically Active, Steroid-Dependent Crohn's Disease," <i>Gastroenterology</i> , 117:1278-1287 (1999).					
	AW	Tromm, A. et al., "Oral Mesalazine for the Treatment of Crohn's Disease: Clinical Efficacy with Respect to Pharmacokinetic Properties," <i>Hepato-Gastroenterology</i> , 46:3124-3135 (1999).					
	AX	Katz, S., "Update in Medical Therapy in Inflammatory Bowel Disease: A Clinician's View," <i>Digestive Diseases</i> , 17:163-171 (1999).					
	AY	Lang, K.A. and Peppercorn, M.A., "Promising New Agents for the Treatment of Inflammatory Bowel Disorders," <i>Drugs R&D</i> , 1(3):237-244 (1999).					
	AZ	Rutgeerts, P.J., "Review Article: Efficacy of Infliximab in Crohn's Disease-Induction and Maintenance of Remission," <i>Aliment Pharmacol. Ther.</i> , 13(Suppl. 4):9-15 (1999).					
	AR2	Rutgeerts, P.J and Targan, S.R., "Summary," <i>Aliment Pharmacol. Ther.</i> , 13(Suppl. 4):38 (1999).					
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	AS2	Podolsky, D.K. et al., "Attenuation of Colitis in the Cotton-top Tamarin by Anti- α 4 Integrin Monoclonal Antibody," <i>J. Clin. Invest.</i> , 92:372-380 (1993).	
	AT2	Yacyshyn, B.R. et al., "Crohn's Disease, Ulcerative Colitis, and Normal Intestinal Lymphocytes Express Integrins in Dissimilar Patterns," <i>Gastroenterology</i> , 107:1364-1371 (1994).	
	AU2	Salmi, M. et al., "Aberrant Binding of Lamina Propria Lymphocytes to Vascular Endothelium in Inflammatory Bowel Diseases," <i>Gastroenterology</i> , 106:596-605 (1994).	
	AV2	Hynes, R.O., "Integrins: Versatility, Modulation, and Signaling in Cell Adhesion," <i>Cell</i> , 69:11-25 (1992).	
	AW2	Springer, T.A., "Traffic Signals for Lymphocyte Recirculation and Leukocyte Emigration: The Multistep Paradigm," <i>Cell</i> , 76:301-314 (1994).	
	AX2	Berlin, C. et al., " α 4 Integrins Mediate Lymphocyte Attachment and Rolling Under Physiologic Flow," <i>Cell</i> , 80:413-422 (1995).	
	AY2	Hamann, A. et al., "Role of α 4-Integrins in Lymphocyte Homing to Mucosal Tissues In Vivo," <i>J. of Immunology</i> , 152:3282-3293 (1994).	
	AZ2	Lazarovits, A.I. et al., "Lymphocyte Activation Antigens," <i>J. of Immunology</i> , 133(4):1857-1862 (1984).	
	AR3	Berlin, C. et al., " α 4 β 7 Integrin Mediates Lymphocyte Binding to the Mucosal Vascular Addressin MAdCAM-1," <i>Cell</i> , 74:185-195 (1993).	
	AS3	Andrew, D.P. et al., "Distinct but Overlapping Epitopes Are Involved in α 4 β 7-Mediated Adhesion to Vascular Cell Adhesion Molecule-1, Mucosal Addressin-1, Fibronectin, and Lymphocyte Aggregation," <i>J. of Immunology</i> , 153:3847-3861 (1994).	
	AT3	Lazarovits, A.I. and Karsh J., "Differential Expression in Rheumatoid Synovium and Synovial Fluid of α 4 β 7 Integrin," <i>J. of Immunology</i> , 151:6482-6489 (1993).	
	AU3	Pals, S.T. et al., "Expression of the Mucosal Homing Receptor α 4 β 7 in Malignant Lymphomatous Polyposis of the Intestine," <i>Gastroenterology</i> , 107:1519-1523 (1994).	
	AV3	Schweighoffer, T. et al., "Selective Expression of Integrin α 4 β 7 on a Subset of Human CD4 ⁺ Memory T Cells with Hallmarks of Gut-Trophism ¹ ," <i>J. of Immunology</i> , 151(2):717-729 (1993).	
	AW3	Postigo, A.A. et al., " α 4 β 7 Integrin Mediates B Cell Binding to Fibronectin and Vascular Cell Adhesion Molecule-1," <i>J. of Immunology</i> , 151(5):2471-2483 (1993).	
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	AX3	Erle, D.J. et al., "Expression and Function of the MAdCAM-1 Receptor, Integrin $\alpha 4 \beta 7$, on Human Leukocytes ¹ , <i>J. of Immunology</i> , 153:517-528 (1994).	
	AY3	Tiisala, S. et al., " $\alpha_5 \beta_1$ and $\alpha_4 \beta_7$ Integrins Associated with Intraepithelial and Mucosal Homing, are Expressed on Macrophages*," <i>Eur. J. Immunol.</i> , 25:411-417 (1995).	
	AZ3	Wan, H.C. et al., "Expression of $\alpha 4 \beta 7$ Integrin on Eosinophils and Modulation of $\alpha 4$ -Integrin-Mediated Eosinophil Adhesion Via CD4," <i>Int. Arch Allergy Immunol.</i> , 107:343-344 (1995).	
	AR4	Teague, T.K. et al., "Integrin $\alpha 4 \beta 7$ Co-Stimulation of Human Peripheral Blood T Cell Proliferation," <i>Cell Adhesion and Communication</i> , 2:539-547 (1994).	
	AS4	Briskin, M.J. et al., "MAdCAM-1 has Homology to Immunoglobulin and Mucin-Like Adhesion Receptors and to IgA1," <i>Nature</i> , 363:461-464 (1993).	
	AT4	Yang, Y. et al., "Construction and Adhesive Properties of a Soluble MAdCAM-1-Fc Chimera Expressed in a Baculovirus System: Phylogenetic Conservation of Receptor-Ligand Interaction," <i>Scand. J. Immunol.</i> , 42:235-247 (1995).	
	AU4	Briskin, M.J. et al., "Structural Requirements for Mucosal Vascular Addressin Binding to Its Lymphocyte Receptor $\alpha 4 \beta 7$," <i>J. of Immunology</i> , 156:719-726 (1996).	
	AV4	Berg, E.L. et al., "L-Selectin-Mediated Lymphocyte Rolling on MAdCAM-1," <i>Nature</i> , 366:695-698 (1993).	
	AW4	Salmi, M. et al., "Dual Binding Capacity of Mucosal Immunoblasts to Mucosal and Synovial Endothelium in Humans: Dissection of the Molecular Mechanisms," <i>J. Exp. Med.</i> , 181:137-149 (1995).	
	AX4	Bednarczyk, J.L. et al., "Identification of a Combinatorial Epitope Expressed by the Integrin $\alpha 4 \beta 1$ Heterodimer Involved in the Regulation of Cell Adhesion," <i>J. of Biological Chemistry</i> , 269(11):8348-8354 (1994).	
	AY4	Podolsky, D.K., "Inflammatory Bowel Disease," <i>The New England Journal of Medicine</i> , 325(13):928-937 (1991).	
	AZ4	Tidswell, M. et al., "Structure-Function Analysis of the Integrin β_7 Subunit Identification of Domains Involved in Adhesion to MAdCAM-1 ^{1,2} , <i>The Journal of Immunology</i> , 159:1497-1505 (1997).	
	AR5	Podolsky, D.K., "Inflammatory Bowel Disease," <i>The New England Journal of Medicine</i> , 325(14):1008-1016 (1991).	
	AS5	Gordon, F.H. et al., "Treatment of Active Ulcerative Colitis with a Recombinant Humanised Antibody to $\alpha 4$ Integrin (Antegren™)," <i>Gastroenterology</i> , 116(4) Part 2:A726 (1999).	
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PTO-1499 REPRODUCED		ATTORNEY DOCKET NO. 1855.2007-010	APPLICATION NO.
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		FILING DATE	GROUP
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AT5	Gordon, F.H. et al., "Randomised Double-Blind Placebo-Controlled Trial of Recombinant Humanised Antibody to α 4 Integrin (Antegren™) in Active Crohn's Disease," <i>Gastroenterology</i> , 116(4) Part 2:A726 (1999).	
	AU5	Lin Ko-Chung et al., "Very Late Antigen 4 (VLA4) Antagonists as Anti-Inflammatory Agents," <i>Current Opinion in Chemical Biology</i> , 2(4):453-457 (1998).	
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